DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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AUG 22 1994

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Re: Effexor®
Docket No. 94E-0098

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DEPUTY ASSISTANT COMMISSIONER FOR PATENTS

The Honorable Bruce Lehman
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks
Washington, D.C. 20231

Dear Commissioner Lehman:

This is in regard to the application for patent term extension for U.S. Patent No. 4,535,186, filed by American Home Products Corporation under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Effexor®, the human drug product claimed by the patent.

The total length of the regulatory review period for Effexor® is 2,959 days. Of this time, 1,981 days occurred during the testing phase and 978 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: November 23, 1985.

   FDA has verified the applicant's claim that the date the investigational new drug application (IND) became effective was November 23, 1985.

2. The date the application was initially submitted with respect to the human drug product under subsection 505(b) of the Federal Food, Drug, and Cosmetic Act: April 26, 1991.

   The applicant claims June 18, 1991 as the date the new drug application (NDA) for Effexor® (NDA 20-151)was initially submitted. However, FDA records indicate that NDA 20-151 was initially submitted on April 26, 1991.

3. The date the application was approved: December 28, 1993.

   FDA has verified the applicant's claim that NDA 20-151 was approved on December 28, 1993

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Stuart L. Nightingale

Stuart L. Nightingale, M.D.
Associate Commissioner
for Health Affairs

cc: Ronald W. Alice
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